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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/815,388	03/31/2004	Pablo Caviedes	USF-167XC1 7583		
	7590 01/05/200 K LLOYD & SALIW	EXAMINER			
	NAL ASSOCIATION	FORD, ALLISON M			
PO BOX 14295 GAINESVILLE	E, FL 32614-2950	ART UNIT	PAPER NUMBER		
	,	1651			
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary		Applicat	Application No. Applicant(s)					
		10/815,3	88	CAVIEDES ET AL.				
		Examine	r ·	Art Unit				
		Allison M		1651				
Period fo	The MAILING DATE of this communication or Reply	appears on th	e cover sheet with the c	correspondence ad	dress			
WHIC - Exter after - If NC - Failu Any i	ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING assions of time may be available under the provisions of 37 CFF SIX (6) MONTHS from the mailing date of this communication or period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by streply received by the Office later than three months after the med patent term adjustment. See 37 CFR 1.704(b).	ODATE OF T R 1.136(a). In no even riod will apply and valute, cause the ap	HIS COMMUNICATION vent, however, may a reply be tin vill expire SIX (6) MONTHS from blication to become ABANDONE	N. nely filed the mailing date of this co D (35 U.S.C. § 133).				
Status								
1)	Responsive to communication(s) filed on 0	6 October 200	06.					
2a) <u></u> □		This action is	-					
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositi	ion of Claims							
4)⊠	Claim(s) 18,21-26,30,31 and 33-47 is/are p	ending in the	application.					
	4a) Of the above claim(s) <u>40-43</u> is/are withdrawn from consideration.							
5)	5) Claim(s) is/are allowed.							
6)⊠	DIX Claim(s) <u>18,21-26,30,31,33-39 and 44-47</u> is/are rejected.							
7)	Claim(s) is/are objected to.							
8)[_	Claim(s) are subject to restriction an	d/or election	requirement.					
Applicati	on Papers							
9) 🗌	The specification is objected to by the Exam	niner.	·					
. 10)⊠	10)⊠ The drawing(s) filed on <u>31 March 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
_	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority ι	ınder 35 U.S.C. § 119			•	•			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:								
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
	3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
Attachment	t(s)							
1) 🔲 Notic	e of References Cited (PTO-892)		4) Interview Summary	(PTO-413)				
	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08)		Paper No(s)/Mail Da 5) Notice of Informal P	ate				
	r No(s)/Mail Date		6) Other:	a.om ripphoddon				

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DETAILED ACTION

Request for Continued Examination

Applicant's Request for Continued Examination filed 6 October 2006 has been received and entered into the case. Claims 44-47 have been added. Claims 1-17, 19-20, 27-29 and 32 have been cancelled. Claims 18, 21-26, 30-31 and 33-47 remain pending, with claims 40-43 being withdrawn from consideration. Claims 18, 21-26, 30-31, 33-39 and 44-47 have been considered on the merits.

Response to Arguments

Applicants' arguments submitted with the response of 6 October 2006 have been fully considered.

Regarding the objection of claim 23 as failing to further limit claim 21, applicants have amended claim 23 to depend from claim 18; this obviates the grounds of objection.

Regarding the objection to claims 19 and 33 as being substantial duplicates of one another, applicants have cancelled claim 19, thereby obviating the grounds of objection.

Regarding the rejection of claim 35 under 35 USC 112, first paragraph, as lacking enablement for the full scope of the invention, applicants have amended claim 35 so that it no longer prohibits inclusion of any non-living or degenerate cell, but rather requires the presence of at least one cell which will remain viable upon implantation.

Regarding the rejection of claim 39 under 35 USC 112, second paragraph, as being indefinite, applicants have amended claim 39 to more accurately define that the cells are 'supported by said plate'. The term 'supported by' is defined in the specification to include

situations wherein the substrate supports culture medium comprising the cells (See Specification, Pg. 17, ln 24-27); therefore the rejection is withdrawn.

Regarding the rejection of claims 18, 19, 22-26 and 33 under 35 USC 102(a) over Andrews et al, applicants argue that the disclosure of the Andrews et al poster presentation is not applicable as a reference under 35 USC 102(a) because the poster presentation represents the inventors own work and thus is not "by another"; applicants submitted a declaration under 37 CFR 1.132 to this effect.

Initially it is noted that claim 19 is now cancelled; and therefore the rejection of such is moot.

In response to the arguments, the first declaration of Dr. Caviedes has been re-reviewed. The declaration is sufficient to remove P. Venegas from consideration as "another"; however, the problem remains that T. Freeman, C. Arriagada and J. Rivera remain as inventors on the subject application, but are not listed as authors on the Andrews et al presentation. The declaration of Dr. Caviedes sets forth the contributions of each of T. Freeman, C. Arriagada and J. Rivera; however, it appears the work of each of these inventors was directed to methods of optimizing the cell aggregates and methods of optimizing transplantation of the neuronal aggregates into Parkinson's patients. The invention as currently *claimed* is not directed to methods of creating the culture or methods of transplanting the cell aggregates as part of a therapy; therefore, the disclosure of the Andrews et al poster presentation does not represent the work of T. Freeman, C. Arriagada and/or J. Rivera, and thus the reference does not merely disclose 'applicants' own work,' but rather work 'by another.' Therefore the declaration is not sufficient to overcome the rejection under 35 USC 102(a) because the Andrews et al reference, as far as it discloses the currently claimed invention, is 'by another.'

Regarding the rejection over Takazawa et al under 35 USC 103(a) applicants argue that. Applicants argue Takazawa et al only provide empirical evidence of successfully culturing kidney cells, and thus they argue there was no expectation of success for culture of neuronal cells of the CNS in the method of Takazawa et al. Applicants argue the large number and varied types of cell species disclosed by Takazawa et al is not supported as enabled by the limited examples of Takazawa et al. Applicants further submit a second declaration by Dr. Caviedes supporting the position that the disclosure of Takazawa et al does not provide a reasonable expectation of success for all cell types listed. Applicants further present evidence (Exhibits B and C) as showings of unexpected results; specifically arguing that neuronal cells of the cell culture of the invention produced better results when implanted into the striatum of rats previously lesioned in the nigrostraital pathway with 6-hydroxydopamine (6-OHDA).

In response to applicants' argument that Takazawa et al is not enabled for all types of adherent animal cells, relying on the fact that Takazawa et al have only showed a single experiment with kidney cells, please note that when considering the factors relating to determination of non-enablement, if all the other factors point towards enablement, then the absence or low number of working examples will not by itself render the invention non-enabled. Dr. Caviedes' declaration to the same effect has been considered, but, for the same reasons, the absence of empirical data supporting all possible embodiments is not sufficient to show nonenablement. The declaration has been given full consideration, but in the absence of any substantive reasoning or supportive evidence, the statement is not sufficient to show nonenablement of a patent. To present a valid reason why the teachings of Takazawa et al are not valid for their entire disclosed scope one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate the one working example across the entire scope of the invention.

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In response to applicants' argument of unexpected results, including the declaration by Dr. Caviedes regarding the experiments presented in Exhibits B and C, it is noted that the current claims are directed to a cell culture composition, not a method of treating neurological disorders or any method involving implantation of neuronal cell aggregates. The issue at hand is currently whether the culture media disclosed by Takazawa et al is capable of maintaining process forming neuronal cells of the central nervous system in suspension culture, not the ability of the cultured cells to integrate into the nigrostratium pathway of test animals and to affect the apomorphine-induced circling behavior. The experimental results presented in Exhibits B and C are not considered to demonstrate 'unexpected results' because they are not commensurate in scope with the invention as currently claimed. The comparisons between the RCSN-3 cells, cultured in the presence of UCTH-1 media (which is assumed to comprise less than 100 uM calcium, though the specification never defines UCTH-1 media) and RCSN-3 cells cultured under "standard" culture conditions is not sufficient to show any unexpected or novel properties of the currently claimed culture medium compared to that of Takazawa et al, as the "standard culture conditions" do not replicate the culture conditions disclosed by Takazawa et al.

In submitting evidence asserted to establish unobvious results, there is a burden on an applicant to indicate how the examples asserted to represent the claimed invention are considered to relate to the examples intended to represent the prior art and, particularly, to indicate how those latter examples do represent the closest prior art. See *In re Borkowski*, 595 F.2d 713, 184 USPQ 29 (CCPA 1974); *In re Goodman*, 339 F.2d 228, 144 USPQ 30 (CCPA 1964). The evidence relied upon should also be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter "as a class." *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971); *In re Hostettler*, 429 F.2d 464, 166 USPQ 558 (CCPA 1970). See, also, *In re Lindner*, 457 F.2d 506, 173 USPQ 356 (CCPA 1972). It should also be established that the differences in the results are in fact unexpected and

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unobvious and of both statistical and practical significance. *In re Merck*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Klosak*, 455 F2d 1077, 173 UAPQ 14 (CCPA 1972); *In re D'Ancicco*, 429 F.2d 1244, 169 USPQ 303 (CCPA 1971). *Ex parte Gelles*, 22 USPQ2d 1318 (BPAI 1992).

Applicants arguments are therefore not found persuasive, the rejections of record stand.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18, 22-26 and 33 stand rejected under 35 U.S.C. 102(a) as being anticipated by Andrews et al (Poster presentation from Cell Culture and Engineering Conference in Snowmass, CO; 2002).

Andrews et al teach culturing RCSN-3 cells (rat neurons from the central nervous system) in microbiological plates (which applicant calls a solid substrate which support the culture medium) to produce a mass suspension culture wherein the cells do not adhere to the substrate, but form three-dimensional aggregates. The microbiological plates were plastic, and were untreated by any cell attachment treatments or cell attachment factors (as evidenced by their comparison to 'standard conditions' comprising glass or plastic treated plates). Andrews et al teach the neuronal cells were maintained in an optimized media comprising low serum (2%) supplemented with hormones (insulin, progesterone), proteins (transferrin), and trace elements (Sodium selenite, putrescine). Andrews et al do not teach calcium as a component of the media; therefore, in the absence of any evidence showing calcium was present in the media used by

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Andrews et al, the media of Andrews et al is considered to be calcium free (Claims 18, 22-26 and 33). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 21-26, 30, 31, 34-39 and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takazawa et al (US Patent 5,219,752), in view of Studer et al (WO 00/05343), and further in view of Boss et al (US Patent 5,411,883).

Takazawa et al teach an animal cell culture wherein adherent animal cells are cultured in such conditions so that the cells do not adhere, but remain in suspension as single cells or small cell clumps. Takazawa et al teach the cells remain in suspension as single cells, or in small cell aggregates of 1.1-50 cells on average (which applicant calls not substantially adhering to the substrate) (See Takazawa et al, col. 14, ln 33-43). Takazawa et al teach a wide variety of normally adherent animal cells can be maintained in suspension culture by the means of their invention, the types of cells include several cell types derived from the nervous system, including rat glial cells (a category of neuronal, process-forming cells) (ATCC No. CCL 107) and mouse neuroblastomas (neurons) (ATCC No. CCL 131) (See Takazawa et al, Table spanning col. 5-12).

While Takazawa et al does not specifically teach process-forming cells of the central nervous system, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the culture method of Takazawa et al was applicable to any normally adherent animal cell cultures, this assertion is based on their extensive, non-limiting list of cell

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types described as applicable in their claimed methods. It is noted that Takazawa et al does teach process-forming cells from the peripheral nervous system (mouse neuroblastomal cells ATCC No. CCL 131) and other neuronal cells, including cells derived from rat glia (ATCC No. CCL 107); therefore, one of ordinary skill in the art would have had a reasonable expectation that neuronal, process-forming cells from the central nervous would also have been within the enabled scope of the invention of Takazawa et al. Methods of culturing process-forming cells from the central nervous system in aggregate cultures were desirable at the time the invention was made. for example, Studer et al teach formation of dopaminergic cells (neuronal process forming cells from the CNS) in aggregate culture is desirable because it allows for recovery of the cultured cells without use of enzymatic digestion, which may damage the cells (See Studer et al, Pg. 3, In 16-25). Use of dopaminergic cells in large numbers was desirable for treatment of various diseases and conditions, including Parkinson's, Alzheimer's and Huntington's disease; production of dopaminergic cells in vitro allows for production of a greater number of cells with less ethical concerns (as such cell samples are otherwise obtained from fetuses and 3-5 fetuses are required to accumulate a sufficient number of cells for transplantation) (See Studer et al, Pg. 1, ln 12- Pg 2, ln 11). Alternatively, such process forming neuronal cells from the CNS are also valuable in culture for the proteins and chemical which they secrete. For example, dopaminergic neurons secrete dopamine and tyrosine hydroxylase (See Studer et al, Pg. 8, ln 4-10). Production of such chemicals would be useful for studies on how these drugs affect the body and finding potential therapies for those diseases listed above. Therefore, one of ordinary skill in the art would have been motivated to utilize the suspension culture method of Takazawa et al to produce cultures of dopaminergic cells in suspension culture, thereby creating cell cultures comprising neuronal, process forming cells of the CNS in aggregate form (wherein the cells within the aggregates are living) which could either be recovered from culture for transplantation in vivo

(Claim 35), or maintained in culture for production of drugs and bioactive agents specific to those cells.

The cell culture of Takazawa et al further includes serum-free media with a calcium ion (Ca²⁺) concentration of 0.002 mM to 0.3 mM (2uM to 300uM), preferably 0.02 mM to 0.25mM (20uM to 250uM) (See Takazawa et al col. 13, ln 66-col. 14, ln 17). Though the concentration of calcium ions taught by Takazawa et al has a higher upper limit than that which is currently claimed, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amount calcium ion to be included in the cell culture of Takazawa et al as a matter of routine experimentation (Claims 18, 26, 36-38, 44-47). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of calcium ions in the cell culture with a reasonable expectation for successfully obtaining a cell culture that can effectively produce active biological agents secreted from the cultured cells in a higher quantity than possible in adherent cultures within the same culture vessel. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Specifically note that where the claimed ranges overlap, such as in the instant case, or lie inside ranges disclosed by the prior art a prima facie case of obviousness exists. See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Therefore, though Takazawa et al claim a calcium ion concentration of 0.002mM to 0.3mM (2uM to 300uM), preferably 0.02mM to 0.25mM (20uM to 250uM) Ca²⁺; it would have been prima facie obvious to optimize this concentration to below 100uM or 50uM.

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The cell culture of Takazawa et al further comprised a cell culture vessel (which applicant calls a solid substrate) (See Fig. 1). No cell attachment treatments or cell attachment factors are included; thus the cell culture vessel (solid substrate did not comprise any charged molecules or treatment on its surface). Though Takazawa et al disclose a culture vessel (which applicant calls a solid substrate) and provide a drawing of the culture device, they are silent on the exact material of the culture vessel. The culture vessel of Takazawa et al was designed to automatically cycle the culture medium to and from the cell culture; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a standard, microbiological grade culture vessel, such as a Petri dish, flask, bottle, plate, tube, or vial comprised of untreated polystyrene plastic, as polystyrene is particularly useful for resisting adhesion (See Studer et al, Pg. 9, ln 3-17) (Claims 21-25 and 39). One of ordinary skill in the art would have been motivated to use any form of a microbiological grade culture dish because these types of culture vessels are the standard used in cell culture and are available from a variety of laboratory product retailers. One would further have been motivated to use such basic culture vessels instead of the automated device of Takazawa et al in order to save money, as an automated machine would be more expensive, and in order to be able to change the culture medium according to the growth rate of the cells, as opposed to a scheduled media change as is done by automated systems. One of ordinary skill in the art would have been motivated to use untreated microbiological grade (as opposed to tissue culture grade) culture vessels so as to prevent/reduce cell adhesion to the solid substrates; as Takazawa et al desire for the cells to not adhere in a monolayer, but stay in a mass suspension (See Takazawa et al col. 1, ln 55-col. 2, ln 16). One would expect success using any suitable, untreated, microbiological grade untreated polystyrene culture dish to create the cell culture of Takazawa et al because the cells of Takazawa et al are not intended to adhere to the substrate, but rather to be prevented from adhering based on

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the low concentration of calcium. Additionally, because adhesion is not desired, one would expect successfully decreasing adhesion by using culture dishes not treated to promote adhesion.

Regarding the size of the cells aggregates which are formed by the method of Takazawa et al, which can be performed using human dopaminergic cells, such as suggested by Studer et al, Takazawa et al is silent on the size of the aggregates in the suspension. However, at the time the invention was made it would have been well within the purview of one of ordinary to manipulate the size of the cell aggregates. In support, Boss et al teach a similar method of producing aggregates of dopaminergic neuronal cells in suspension culture; Boss et al further teach the size of the aggregates can be adjusted by manipulating the number of cells per culture (by controlling both the number of cells initially seeded and the initial volume of culture medium) (See Boss et al, col. 7, ln 40-54). Boss et al also teach that minimizing the number of necrotic cells in the center of the aggregates helps to ensure lower initial plating densities and maintaining smaller aggregate size. Boss et al teach a slightly lower aggregate size range than Studer et al, of 100um-1000um, as opposed to 0.6-1.2mm (600-1200um) (See Boss et al, col. 5, ln 49-51). The size range of Boss et al encompasses the claimed size range of 150um-200um; please note that cases where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists (Claim 34). In re Wertheim, 541 F.2d 257, 191 USPO 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990). Therefore, based on the teachings of Boss et al regarding optimization of the size of the aggregates in suspension culture, one of ordinary skill in the art would expect to be able to successfully manipulate the size of neuronal cell aggregates produced by the method of Takazawa et al/Studer et al as desired. One would be motivated to optimize the size of the cell aggregates to a size range appropriate for the intended use. For example, in cases where the neuronal cell aggregates are to be recovered from culture and used in therapeutic treatments involving injection of the dopaminergic cell-containing aggregates directly into the brain of a patient in need thereof, as taught by Studer et al (See Studer

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et al, Pg 4, ln 32-Pg. 5, ln 3 & Pg. 13, ln 1-Pg. 14, ln 10), Boss et al teach that manipulation of the size of aggregates allows one to formulate the aggregates so that they can pass unobstructed through a needle or catheter (See Boss et al, col. 5, ln 40-51). Therefore, for the therapeutic treatments suggested by Studer et al one would be motivated to manipulate the size of the aggregates formed in the cultures of Takazawa et al, and one would have expected success in doing such optimization, based on the teachings of Boss et al (Claim 34).

Finally, though Takazawa et al do not teach co-culturing dopaminergic cells with a second cell type, wherein the second cell type is either another process-forming cell, such as other neuronal cells, or are non-process-forming cells, it would have been obvious to one skilled in the art at the time the invention was made to include multiple cell types that are capable of growing in the same general culture conditions in order to obtain a mixture of bioactive products from two or more cell types (Claims 30 and 31). Takazawa et al create the suspension culture in order to produce biologically active substances, for example dopamine and tyrosine hydroxylase from dopaminergic cells, in higher concentrations than permitted by adherent culture, based on the fact that more cells per volume can be maintained in suspension culture than can be maintained in adherent culture (See Takazawa et al, col. 4, ln 37-60). Thus by culturing two or more different cell types together, the collected culture medium will comprise a mixture of growth factors and proteins that can subsequently be used for future cell culture. By culturing two or more cell types together one saves the time and energy on culturing two separate cell populations and then combining the biologically active products obtained therefrom. One of ordinary skill in the art would be motivated to use mixtures including two or more types of process-forming cells or one type of process-forming cell and one type of non-process forming cell in order to create different cocktails of growth mixtures and hormones that would be useful for future cell cultures and experimentations. One would expect success because co-culturing cells is well known in the art; one of ordinary skill would be able to select one or more cell types that could successfully be

cultured together with the dopaminergic cells described above, and have a reasonable expectation of successfully obtaining a biologically active substance containing a combination of growth factors and other secreted proteins and hormones from each cell type (for example, dopamine and tyrosine hydroxylase, which are secreted from dopaminergic neurons (See Studer et al. Pg. 8, ln 4-10)). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571/2